As a retired EPA toxicologist, I know first hand the frustrations of having to deal with epidemiological reports. However, I believe epidemiological reports are valuable but more critical initial review is needed. Today I hope to present a path forward.

The animal studies required to support the registration of a pesticide follow strict, quality assurance, good laboratory practices, ethics and reporting standards. Multiple layers of primary and secondary reviewers are identified and sign the review documents.

Epi reports have a mixed bag of standards for GLP, quality assurance, ethics and reporting. They are often accepted at their face value without documentation of independent review. There is no way to verify the procedures or results presented and the EPA reviewers are not identified.

This is unfair to the public!

Historically, I would like to mention two situations where a more critical initial evaluation would have prevented social or medical problems.

The first is the book "The Kallikak Family" published in 1912 by Henry Goddard. This book was the foundation of "eugenics" and was "well received" at first but serious social consequences resulted. However, closer examination revealed that much of the interviewing reflected the biases of the interviewers. Goddard later regretted writing the book.

The other is the association of vaccinations with autism that could not be verified. The publisher retracted the original

publication. However, within the past year there was an increase in measles in Minnesota because people feared autism from vaccinations.

With the concepts of disparity in the review of animal versus epidemiological studies and the need to provide a more critical initial review of epi reports, I am proposing that:

An Epidemiology Peer Review Council with the goal of creating a transparent document reflecting a thorough review be established by EPA. This Council will consist of six independent sub-committees with relevant experts as follows:

1. **Ethics**: All aspects of assuring the personal safety and identities of the individuals in the cohorts are protected. Will state clearly why individual protected personal data is or is not needed to make a decision.
2. **Endpoint evaluation:** Relevant experts knowledgeable about the endpoint will discuss factors like how many in a cohort are needed to make a meaningful difference. Identify what is known about how this endpoint can be altered by environment and any known chemicals.
3. **Exposure evaluation**
4. **Statistical evaluation**
5. **Analytical Chemistry**
6. **Animal Toxicity and Structure Activity Correlations**

Each sub-committee will articulate why additional date are or are not needed.

The Council will consist of qualified individuals from EPA, FDA or other agencies and consultants as needed. The Council will consider the reports of the six sub-committees and make their

recommendations especially with regard to additional data needed to support transparent regulatory decisions.

The report of the Council will append each of the six sub-committee reports as well as any dissenting opinions.

The Council owns the decisions and since all responsible individuals will be identified, the report is thus transparent. SAPs may further review the Council report.

In conclusion, controversies associated with epidemiological reports may not be eliminated but the Council should contribute to minimizing these controversies.

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